

## REMARKS

### **I. Summary of the Office Action and this Reply**

Claims 1-11, 13-16 and 28-31 are pending in the application. Allowable subject matter has been acknowledged in claims 4-11 and 13-16.

The Examiner has rejected claims 1-3 and 28-31 under U.S.C. §102(b), asserting that such claims are anticipated by U.S. Patent No. 5,364,370 to Szerlip et al. ("Szerlip").

In this Reply, withdrawn claims 12, 17-27 and 32-53 have been canceled.

### **II. Response to 102 Rejections**

A rejection under 35 U.S.C. §102 is proper only if each and every element of the claim is found in a single prior art reference. MPEP § 2131. The Examiner has rejected claims 1-3 and 28-31 under U.S.C. § 102(b), asserting that each and every element of these claims are found in Szerlip.

#### **Claim 1**

Independent claim 1 recites "a retraction mechanism that automatically moves the needle to the retracted position responsive to releasing the base from the site surface." Contrary to the Examiner's assertion on page 2 of the Action, Szerlip does not disclose such a retraction mechanism.

Szerlip discloses a needle 10, 36 that may be passed through an aperture 18, 44 in a cap 16, 30 to perform an injection. The cap includes an adhesive layer 26, 42 "for

temporarily adhering cap member 16 [42] to a skin surface SS during removal of distal end 12 of needle 10 from the patient." Col. 4, lines 35-38; see col. 5, lines 8-16.

Szerlip further states that:

Adhesive layer 26 ensures that distal needle end 12 is retracted automatically inside cap member 16 upon withdrawal of needle 10 from the patient. Col. 4, lines 39-41. See also, col. 5, lines 13-16.

Szerlip further states that:

This feature serves to ensure that the sharp distal end of the needle is retracted inside the cap member during a withdrawal stroke of the needle. Col. 2, lines 30-32.

Still further, Szerlip states that:

During this insertion and during subsequent withdrawal of the needle 10 from the patient, cap member 16 is maintained in contact with skin surface SS through the compressive action of helical spring 22 and through the adhesive force exerted by layer 26. Col. 4, lines 63-68.

However, Szerlip does not disclose "a retraction mechanism that automatically moves the needle to the retracted position responsive to releasing the base from the site surface." Upon careful examination of the Figures and description of Szerlip, it is apparent that the distal needle end 12 will be "retracted" into the cap member 16 before cap member 16 leaves the skin surface. It is only after the distal needle end 12 is "retracted" into the cap member during withdrawal, that continued withdrawal of the distal needle end/needle assembly will permit movement of the cap and will result in pulling away of the cap member's adhesive layer 26 from the skin surface. Accordingly, the Szerlip device provides that the distal needle end is withdrawn into the cap before the cap is removed from the site surface. Thus, withdrawal to a "retracted" position is not performed in response to releasing the device from the skin surface. This is directly

contrary to the claim language, which requires a retracting mechanism that automatically moves the needle to the retracted position responsive to releasing the base from the site surface.

Further, there cannot be motivation to modify Szerlip to provide the claimed invention because doing so would render the Szerlip device inoperable for its intended purpose and/or change the principle of operation of the Szerlip device, which relies upon withdrawal of the needle into the cap before the device can be released from the skin surface.

For at least this reason, reconsideration and withdrawal of the rejection of claim 1 are requested respectfully.

#### **Claim 28**

Independent claim 28 recites "a retraction mechanism that automatically moves the needle from the extended position to the retracted position, the retraction mechanism being configured to begin moving the needle to the retracted position in response to removal of the needle device from the surface." This is clearly not taught or suggested by Szerlip. As discussed above, and in Szerlip, the Szerlip device's needle begins to be withdrawn into the retracted position well before the cap is removed from the skin surface. The Szerlip device does not begin moving the needle in response to removal of the device from the surface. Szerlip relies upon complete withdrawal of the needle into the "retracted" position before the Szerlip device can begin to be removed from the skin surface.

Further, there cannot be motivation to modify Szerlip to provide the claimed

invention because doing so would render the Szerlip device inoperable for its intended purpose and/or change the principle of operation of the Szerlip device, which relies upon withdrawal of the needle into the cap before the device can be released from the skin surface.

For at least this reason, reconsideration and withdrawal of the rejection of claim 28 are requested respectfully.

### **Claims 2-3 and 29-31**

Claim 2-3 and 29-31 depend from claims 1 and 28, respectively, and are likewise patentable for similar reasons.

Additionally, claim 31 requires that the retraction mechanism "includes a cover member for covering the opening after the needle moves from the extended position to the retracted position." Such a cover is neither taught nor suggested by Szerlip. Szerlip merely discloses a cap member 16, 30 that includes an aperture 18, 44. See Figures 1 and 3. In an operative position, the needle 36 extends through the aperture 18, 44 in the cap 16, 30. See Figures 2 and 9. In the inoperative position, the needle 10, 36 is misaligned with the aperture 18, 44, and thus will not pass through the aperture 18, 44, as best shown in Figures 1 and 3. Thus, while the cap member may cover the sharp needle tip, there is no cover that covers an opening in the housing after the needle moves from the extended position to the retracted position, as claimed. The aperture 18, 44 in the cap 16, 30 of Szerlip is never covered by any cover member; it remains open and uncovered at all times.

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For at least these reasons, reconsideration and withdrawal of the rejection of claims 2-3 and 29-31 are requested respectfully.

### CONCLUSION

In view of the foregoing amendments and remarks, Applicants believe claims 1-11, 13-16 and 28-31 to be patentable and the application in condition for allowance. Applicants respectfully request issuance of a Notice of Allowance. If any issues remain, the undersigned requests a telephone interview prior to the issuance of an action.

Respectfully submitted,

Dated: April 25, 2007

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